Central Illinois Community Blood Bank

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9-14-99

1998 '99 SEP 21 P1:21

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Docket No 99D-2013: Guidance for Industry Cooperative Manufacturing Arrangements for Licensed Biologics [Federal Register: August 3, 1999]

To Whom It May Concern:

Central Illinois Community Blood Bank wishes to take the opportunity to comment on this guidance. We are a moderately sized blood center located in central Illinois collecting approximately 30,000 units of blood a year. We are commenting because we are currently involved in an "alternative manufacturing arrangement" that is not, we believe, adequately described in this guidance.

Central Illinois Community Blood Bank (CICBB) is licensed by the FDA to manufacture whole blood and specific other blood products. We "outsource" infectious disease testing to another FDA licensed blood center. All other steps in the manufacturing process (e.g., collection, labeling, and distribution) are performed at our location. Only the CICBB label appears on licensed products, and CICBB takes responsibility for the safety, purity and potency of these products. We believe that this sort of alternate manufacturing arrangement is typical in blood banking establishments at this time.

- Section IV. Divided Manufacturing Arrangements

Paragraph #2 states that the "FDA will consider package label provisions of 21 CFR 210.63 to be met by placing...the name, address and license number(s) of preceding intermediate product manufacturer(s) participating in the divided manufacturing arrangement in the description section of the product package insert..." CICBB assumes that this means that our contract-testing blood center's identification label would have to appear in the Circular of Information. We believe that this would be confusing to the end user, and would raise questions regarding quality of the product that have previously been addressed by the primary manufacturing establishment (in this case, CICBB). *NOTE: SECTION VI PARAGRAPH #8 SEEMS TO CONTRADICT THIS IDEA (SEE BELOW)*

- Section V. Shared Manufacturing Arrangements

Paragraph #1 states that "Shared manufacturing is an arrangement in which two or more manufacturers are licensed and responsible for specific, different aspects of the manufacture of a product but neither is licensed for all aspects of the product manufacturing...Critical manufacturing steps... that FDA has considered adequate for separate licensure include...required infectious disease testing of blood and blood and

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blood components..." This implies that the blood center that is providing required infectious disease testing cannot be licensed for all aspects of the product. This does not apply because, in our case, CICBB's contract-testing laboratory is licensed to perform all manufacturing steps for its own products and does not hold a separate license for testing of CICBB products. We believe this would cause duplicity of efforts for both the blood centers who perform outsourced testing and the FDA in the performance of pre-licensing inspections, and will increase operating costs to both establishments.

- Section VI. Contract Manufacturing Arrangements

Paragraph #1 states: "For the purposes of this document, contract manufacturing refers to a situation in which a license applicant establishes a contract with another entity(ies) to perform some or all of the manufacture of a product as a service to the license applicant." This section implies that the license applicant (manufacturer) and the contract facility cannot both be licensed blood establishments.

Paragraph #2 states: "Because the applicant assumes responsibility for compliance of the contract site...the applicant should have access to...information from the contract site necessary to assure safety, purity and potency of the product. The applicant should be fully informed of all deviations, complaints and adverse events, as well as the results of all tests and investigations regarding possibly impacting the product." This does not reflect the current relationship between CICBB and it's contract-testing facility. Deviations, complaints and adverse events other than those that directly affect testing for CICBB are often considered proprietary information by blood bank establishments, and as such are not shared with other centers.

CICBB does agree with the statement in paragraph #8 that states: "Because the contract facilities are considered to be under the auspices of the license holder, specific identification of the contractor in the product labeling is not required." The contract between CICBB and our contract facility currently allows for exchange of information regarding the results of proficiency testing, reports resulting from inspections by the FDA or American Association of Blood Banks, and deviation reports directly related to CICBB test runs. We believe that this is currently the industry standard.

We hope these comments are useful in revising this draft guidance into final form. If you have any questions or with to communicate directly with CICBB, please contact Cynthia A. Watson at: 217-753-1530.

Sincerely,

Cynthia A. Watson,

Cynthia A. Watson
Quality Assurance Director

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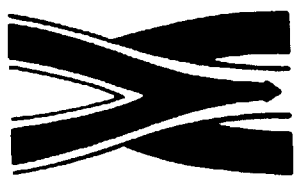

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